

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.		ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/735,289 12/12/2003		Jing Zhu	1676.011US1	9939		
21186	7590	09/06/2006	•	EXAMINER		
SCHWEGN	MAN, LUI	NDBERG, WOES	HAMUD, FOZIA M			
P.O. BOX 2		55402	ART UNIT	PAPER NUMBER		
MINNEAPOLIS, MN 55402				1647		
				DATE MAILED: 09/06/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

		А	pplication No.	Applicant(s)			
Office Action Summary			0/735,289	ZHU ET AL.			
			xaminer	Art Unit			
		F	ozia M. Hamud	1647			
Period fo	The MAILING DATE of this communic	ation appear	rs on the cover sheet w	ith the correspondence	e address		
A SHOWHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOI CHEVER IS LONGER, FROM THE MAI Insions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this commun period for reply is specified above, the maximum stature to reply within the set or extended period for reply will eply received by the Office later than three months afte and patent term adjustment. See 37 CFR 1.704(b).	LING DATE 37 CFR 1.136(a ication. tory period will a 1, by statute, cau	E OF THIS COMMUN  ). In no event, however, may a  pply and will expire SIX (6) MO  use the application to become A	ICATION.  reply be timely filed  NTHS from the mailing date of the MANDONED (35 U.S.C. § 133)	his communication.		
Status							
2a) <u></u>	Responsive to communication(s) filed This action is <b>FINAL</b> . 2b Since this application is in condition fo closed in accordance with the practice	)⊠ This ac r allowance	tion is non-final. except for formal ma	•	the merits is		
Dispositi	on of Claims	•					
5) 6) 7)	Claim(s) <u>1-57</u> is/are pending in the apple 4a) Of the above claim(s) is/are Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) <u>1-57</u> are subject to restriction	withdrawn					
Applicati	on Papers						
10)□	The specification is objected to by the I The drawing(s) filed on is/are: a Applicant may not request that any objection Replacement drawing sheet(s) including the total or declaration is objected to be	a) accepton to the drame correction	wing(s) be held in abeya is required if the drawing	ance. See 37 CFR 1.85(a g(s) is objected to. See 3	7 CFR 1.121(d).		
Priority u	ınder 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
2) Notic 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTC nation Disclosure Statement(s) (PTO-1449 or PT r No(s)/Mail Date		Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application (	(PTO-152)		

Application/Control Number: 10/735,289 Page 2

Art Unit: 1647

## **Election/Restriction**

- 1a. Claims 1-57 are pending.
- 1b. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.
- II. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:2 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.
- III. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with a secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.
- IV. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1

- and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.
- V. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:4 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.
- VI. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:4 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.
- VII. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:5 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.
- VIII. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with a secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:5 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.

Art Unit: 1647

- IX. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:1, classified in class, 530, subclass 351.
- X. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:2, classified in class, 530, subclass 351.
- XI. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:4, classified in class, 530, subclass 351.
- XII. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:5, classified in class, 530, subclass 351.
- XIII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:1 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.
- XIV. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:2 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.
- XV. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:4 and an SLPI

Art Unit: 1647

which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.

- XVI. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:5 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.
- XVII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:1 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.
- XVIII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:2 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.
- XIX. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:4 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.
- XX. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:5 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.

The inventions are distinct, each from the other because of the following reasons:

The method of Groups I-VIII are patentably distinct, because the methods employ polypeptides which possess characteristic differences in structure and function, that is distinct for each invention which cannot be exchanged. The polypeptides of SEQ ID Nos: 1, 2, 4 and 5 appear to be distinct polypeptides, which constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the polypeptides is independent and distinct because no common structural or functional properties are described. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

The inventions of Groups IX-XX are patentably distinct, because the recited polypeptides possess characteristic differences in structure and function, that is distinct for each invention which cannot be exchanged. The polypeptides of SEQ ID Nos: 1, 2, 4 and 5, appear to be distinct polypeptides, likewise the polypeptides of SEQ ID Nos: 7 and 9 are patentably distinct, which constitute a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the polypeptides is independent and distinct because no common structural or functional properties are described. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Inventions I-VIII are related to inventions IX-XX as processes of use and products used. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

Application/Control Number: 10/735,289 Page 7

Art Unit: 1647

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups IX-XX can be used in processes of raising antibodies that bind to the recited polypeptides. Searching the inventions of sequences together would impose serious search burden.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, for example the composition comprising the polypeptide of SEQ ID NO:1, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

Application/Control Number: 10/735,289

Art Unit: 1647

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Having shown that these inventions are distinct for the reasons given above and requirement for separate searches, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR §1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

Application/Control Number: 10/735,289 Page 9

Art Unit: 1647

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

## Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud Patent Examiner Art Unit 1647 27 August 2006

> EILEEN B. O'HARA PRIMARY EXAMINER

leen B.ONava